## In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 19-158V Filed: July 12, 2021

Milton C. Ragsdale, IV, Ragsdale LLC, Birmingham, AL, for Petitioner Christine M. Becer, U.S. Department of Justice, Washington, DC, for Respondent

#### RULING ON ONSET1

#### Oler, Special Master:

On January 30, 2019, Jeffrey Dobyns ("Dr. Dobyns" or "Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, et seq.² (the "Vaccine Act" or "Program"). The petition alleges that the Petitioner developed TM as a result of the flu vaccine he received on December 6, 2016. Pet. at 1.

<sup>&</sup>lt;sup>1</sup> Because this unpublished Ruling contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public. *Id*.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

After carefully considering the evidence presented in this case, to include the medical records, expert opinion, and affidavits, I find that Petitioner's initial symptoms of TM, which included change in gait, lower extremity pain, and difficulty walking, began on December 9, 2016.

#### I. Procedural History

Petitioner filed his Petition on January 30, 2019. Pet., ECF No. 1. Petitioner filed supporting medical records on February 28, 2019 (Exs. 2-9) and on September 12, 2019 (Ex. 13).

Respondent filed his Rule 4(c) Report on March 9, 2020. Resp't's Rep.; ECF No. 17. Respondent argued that this case is not appropriate for compensation because the onset of Petitioner's condition is unclear, as the medical records indicate symptoms began within hours of vaccination up through 72 hours after administration of the flu vaccine. *Id.* at 6. Respondent further stated that "fewer than 48 hours, after vaccination is not medically reasonable for causation." *Id.* at 7.

I held a status conference on March 17, 2020 where I discussed the possibility that I rule on the record concerning the issue of onset. *See* Scheduling Order dated 3/17/2020. Respondent's counsel indicated that a ruling on onset would help to move the case forward, and that the Respondent "did not dispute Petitioner's diagnosis of transverse myelitis ("TM"), just the onset of Petitioner's symptoms." *Id.* Mr. Ragsdale stated he had to confer with his client regarding whether he would consent to a ruling on the record. I ordered Petitioner to file a status report in 30 days articulating his preference for an onset hearing or a ruling on the record. *Id.* 

On April 16, 2020, Petitioner filed a status report indicating he consented to a ruling on the record regarding onset. ECF No. 19. On April 17, 2020, I gave Petitioner a 30-day deadline to submit any additional materials that he would like me to consider. *See* non-PDF Scheduling Order dated 4/17/2020.

On May 18, 2020, Petitioner filed a letter from Dr. William Meador (Ex. 14), Dr. Meador's CV (Ex. 15), and medical literature in support of his position (Exs. 16-25).

On July 17, 2020, Respondent filed a status report pursuant to my order and stated that "Respondent prefers an onset hearing, but given the current difficulties related to Covid-19, respondent will leave it to the court's discretion whether to have an onset hearing or a ruling on the record regarding onset." ECF No. 23.

Petitioner filed a declaration regarding onset on September 3, 2020 (Ex. 28) as well as his motion for a ruling on the record concerning onset. ECF No. 25. Respondent filed a response on October 19, 2020. Petitioner filed a reply on November 2, 2020. This case is now ripe for a fact ruling.

#### II. Petitioner's Medical Records that Pertain to the Issue of Onset

Petitioner received his flu vaccine on December 6, 2016. Ex. 1 at 4. He presented to the emergency room on December 10, 2016 at 0958 complaining of "difficulty ambulating since this

morning." Ex. 4 at 19. The record further indicates that Petitioner "had some pain in his buttocks region that radiated to his lower extremities yesterday. The patient states he sat yesterday at work with his legs propped up. The patient states he woke up this morning at 2 and felt like he was having difficulty walking." *Id*.

On that same day, December 10, 2016, Petitioner visited Dr. Anthony Nichols, a neurologist at UAB. Ex. 5 at 6-10. The records from this visit provide a similar history as the ER records; the UAB records indicate as follows:

This Tuesday, he received his flu vaccine. The next night, he woke up thinking he has a knot in his L leg. He overlooked it and went back to sleep. Yesterday, he had a regular day at work but felt his buttocks were sore. He usually works on his laptop for hours with his legs propped up, so assumed it is most likely because of a bad chair or his posture. He went to sleep, but woke up in the middle of a sound sleep, due to sharp, burning sensation...

#### Ex. 5 at 7.

On December 21, 2016, Petitioner visited TherapySouth for a PT evaluation. During this appointment, he reported "sudden onset of numbness/tingling in feet and lower legs on 12/10/16." Ex. 11 at 2. This record further states that Petitioner "Received flu vaccine. Following 24-72 hours had significantly inc[reased] weakness and LE paresthesias making walking very difficult." *Id*.

On February 27, 2017, Petitioner visited Dr. William Meador, a neurologist. Ex. 6 at 35-40. Petitioner reported that after receiving the flu vaccine,

within 1 or 2 hours he developed a band like pain across his sacral region that did not wrap around to the anterior portions of his groin or legs. He thought this was related to the fact he had been sitting on bleachers for band competitions with his family recently. Throughout the remainder of the week he developed progressive symptoms. This began with some buttocks pain that he again attributed to sitting on metal bleachers. However by late in the week, his colleagues noted that he was having trouble walking. [B]y Friday December 9<sup>th</sup>, he had a notable change in his gait but thought it was related to pain. Later that evening, when he was sleeping, he woke up with a searing pain from his buttocks to his posterior thighs and down into his feet. This was unlike anything he had experienced before.

#### *Id.* at 35-36.

On July 10, 2017, Petitioner again visited Dr. Meador. Ex. 6 at 245. Dr. Meador noted that "The timing of his event following a flu vaccine makes it highly likely that this is a post-vaccination TM event..." *Id.* The record further states that Petitioner initially thought his "symptoms began a few hours [after the vaccine], but on hindsight, he had some back pain from sitting on metal bleachers all week. It was not until 3 days later that he developed true neurologic issues – colleague noted he couldn't walk normally." *Id.* 

#### III. Expert Opinion

Dr. Meador provided a letter in support of Petitioner's claim. Ex. 14. In this letter, Dr. Meador distinguished between Petitioner's symptoms of tightness and pain that he experienced close-in-time to his vaccination, and the signs and symptoms of urinary retention, change in gait, and weakness that Petitioner experienced beginning on December 9, 2017. He stated that

Though on review of the records it may seem that Dr. Dobyns' symptoms began immediately after the vaccination, he had a plausible explanation of back and leg symptoms that he had experience[d] before as a result of sitting for prolonged periods on metal bleachers. He reported to me that he had experienced similar symptoms before after sitting on such surfaces at length. The symptoms that are directly attributable to TM – such as urinary retention, change in gait, and weakness in his legs - did not begin until 12/9/16 as best I can tell.

Id.

#### IV. Affidavits that Address the Issue of Onset

Petitioner submitted one affidavit and one declaration in support if his claim. In his initial affidavit, Petitioner stated that he received his flu vaccine on December 6, 2016 and in the afternoon of the third day following his vaccination, a work colleague noticed that he was "walking with an unusual gait." Ex. 2 at 1. Petitioner also noted that he had experienced some "intermittent discomfort" while sitting in the bleachers at a high school event for his children earlier in the day. *Id.* 

He went to bed that evening and woke up at around 0200 on December 10, 2016. Ex. 2 at 1. At that time, Petitioner stated he was experiencing severe pain in his pelvis and legs. *Id.* He said that the pain felt like "flame-throwers shooting from [his] pelvis down [his] legs." *Id.* He went back to bed and awoke at 0730. *Id.* At that time, Petitioner experienced weakness and numbness from his toes to his knees and difficulty urinating. *Id.* Later that morning, Petitioner's wife drove him to the hospital, and he was transported to the UAB Hospital later that same day. *Id.* at 1-2.

Petitioner filed a declaration regarding onset on September 2, 2020. Ex. 28. Petitioner stated that that he received the flu vaccine on December 6, 2016 just after eating lunch and before the shift change at 1500. Ex. 28 at 1. Petitioner further stated that during the evenings of December 6-8, he attended school band concerts for his three sons. *Id.* The concerts were in the school gym and seating was on the bleachers. *Id.* Petitioner stated that at some point following the concerts, he noticed some soreness in his buttocks. *Id.* He stated, "It was nothing out of the ordinary, and exactly the kind of soreness I would have expected after spending several hours over the course of these evenings sitting on bleachers." *Id.* 

Petitioner further described that during the night of December 7, 2016, he awoke with a "charlie horse" type of pain in his left leg. Ex. 28 at 1. Petitioner described this pain, stating, "It was a type of pain that I routinely experienced and it resolved easily. It was nothing like the event that I later experienced during the early morning hours of December 10<sup>th</sup>." *Id*.

On December 9, 2016, Petitioner was scheduled to begin work at 1500. Ex. 28 at 1. He stated that he had been in his office earlier in the day working on his laptop, in a seated position with his legs propped up on his desk. *Id.* During the 1500 shift change, Petitioner stated that he was walking with a work colleague who remarked that he was walking with a wide gait. *Id.* Petitioner averred that this was the first time he noticed a change in his gait. *Id.* He left work at 1900 and went to bed at 2100. *Id.* 

He woke up at around 0200 on December 10, 2016 and was experiencing a sharp burning sensation in his back that radiated bilaterally down his sciatic nerve. Ex. 28 at 1. He tried to get out of bed but had difficulty walking "due to weakness and a wide gait." *Id.* Petitioner stated that he took some ibuprofen and sat in a massage chair for approximately one hour to help with the pain. *Id.* at 2. He went back to sleep and awoke at 0730. *Id.* Petitioner stated the pain was better, but when he tried to stand, he experienced weakness and a wide gait. *Id.* He also had difficulty urinating. *Id.* He decided to go to the emergency room. *Id.* 

#### V. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claim by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

In order to make a determination concerning factual issues, such as the timing of onset of petitioner's alleged injury, the special master should first look to the medical records. "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993); Lowrie v. Sec'y of Health & Hum. Servs., No. 03-1585V, 2006 WL 3734216, at \*8 (Fed. Cl. Spec. Mstr. Nov. 29, 2006). Medical records created contemporaneously with the events they describe are presumed to be accurate and complete. Doe/70 v. Sec'y of Health & Hum. Servs., 95 Fed. Cl. 598, 608 (2010).

Contemporaneous medical records generally merit greater evidentiary weight than oral testimony; this is particularly true where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992)(citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight")). "Written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later." *Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

However, there are situations in which compelling oral testimony may be more persuasive than written records--for instance in cases where records are found to be incomplete or inaccurate.

Campbell, 69 Fed. Cl. at 779 ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); Lowrie, 2005 WL 6117475, at \*19 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting Murphy, 23 Cl. Ct. at 733).

When witness testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. La Londe v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). A special master making a determination whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at a hearing must have evidence suggesting the decision was a rational determination. Burns by Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

#### VI. Findings of Fact

Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a preponderance of the evidence. § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

The question to be resolved is when Petitioner's initial symptoms associated with his TM began. Petitioner contends that they began on December 9, 2016 when he exhibited a change in gait, lower extremity pain, and difficulty walking. Pet'r's Mot. at 1. Respondent contends Petitioner's symptoms associated with TM began within 48 hours of vaccination. Resp't's Resp. at 4. To support his position, Respondent cited to the fact that Petitioner experienced leg cramping the night of December 7, 2016; Petitioner mentioned band-like pain around the sacral region within hours of vaccination; and the fact that the records note progressive symptoms developing over the following days. *Id*.

After reviewing the medical records and affidavits presented in this case, and after my careful examination of the record as a whole, I find there is preponderant evidence that the onset of Petitioner's initial symptoms associated with TM began on December 9, 2019. I base this finding on Petitioner's medical records, the opinion of his treating neurologist, Dr. Meador, and on Petitioner's affidavits.

It is clear from the medical records and the affidavits that Petitioner experienced a change in gait which began on December 9, 2016 at around 1500. See Ex. 6 at 35 ("his colleagues noted

that he was having trouble walking"); Ex. 28 at 1 ("When it was time to make the 3:00 pm shift change, I was walking with a colleague, Dr. Victoria Belopolsky. While we were walking, she commented that I was walking with a wide gait."). He then experienced leg weakness on or about 0200 on December 10, 2016 and urinary retention at around 0730 on December 10, 2016. See Ex. 4 at 9 ("Pt woke up this am at 0200 with bilateral lower extremity numbness/weakness."). Ex. 28 at 2 ("I also had difficulty urinating for the first time that morning"). The timeline surrounding these signs and symptoms is not in dispute. Further, it is not in dispute that Petitioner's gait change, leg weakness, and urinary retention were related to his TM.

The question that I must resolve is whether Petitioner's band-like pain around the sacral region that he experienced shortly after vaccination and the leg pain/tightness that awoke him during the night of December 7, 2016 were also symptoms associated with the onset of Petitioner's TM.

In his affidavit and later in his declaration, Petitioner stated that he attended school band concerts for his children during the evenings of December 6, 7, and 8. Ex. 28. The concerts were in the school gym and seating was on the bleachers. *Id.* Petitioner attributed the pain he experienced after his vaccination to sitting at these concerts for prolonged periods of time. He stated that this pain "was nothing out of the ordinary, and [was] exactly the kind of soreness I would have expected after spending several hours over the course of these evenings sitting on bleachers." *Id.* Petitioner told Dr. Meador "that he had experienced similar symptoms before after sitting on such surfaces at length." Ex. 14.

With respect to the pain in his leg that awoke Petitioner during the night of December 7, 2016, Petitioner described his pain as a "charlie horse". Ex. 28 at 1. He further stated that it was a type of pain that he had frequently experienced and that it resolved quickly. *Id*.

While it is possible these two episodes of pain represented the onset of Petitioner's TM, I do not find there is preponderant evidence in support of that finding. I am particularly persuaded by Petitioner's treating neurologist, Dr. Meador, who opined that "Dr. Jeff Dobyns' clinical event began 3 days after his vaccination when he developed trouble walking and weakness in his legs and urinary retention." Ex. 14 at 3. While Dr. Meador considered that the symptoms Petitioner experienced in the first couple of days post-vaccination may have been associated with his TM, he ultimately concluded that these symptoms were reasonably explained by the fact that Petitioner sat for prolonged periods of time on metal bleachers. *Id.* at 1. This opinion, when considered in conjunction with Petitioner's medical records and affidavits, is persuasive.

#### VII. Conclusion

I find that the affidavits submitted by and on behalf of Petitioner along with the medical records and the opinion of Dr. Meador work in concert to provide preponderant evidence that the initial symptoms of Petitioner's TM began on December 9, 2016.

The following is therefore ORDERED:

By no later than <u>August 11, 2021</u>, the parties shall file a joint status report updating me on their proposed next steps in the case based on the facts articulated in this ruling.

### IT IS SO ORDERED.

s/ Katherine E. Oler Katherine E. Oler Special Master